

**REMARKS**

Claims 1, 3, 6, 8, 11, 26, 28, 42-47 and 49 are currently pending. Claim 1, 11, 26, 42, 45 and 49 have been amended. Claim 1 has been amended wherein the third loop containing section extends in a continuous band of loops around the circumference of the stent, and to further define the relationship between the first, second and third loop containing sections. Claim 11 has been amended to define the third loop containing section as formed of a continuous pattern, and further to correct grammatical errors. Claim 42 and Claim 45 have been amended to correct obvious typographical errors. Finally, Claim 26 has been amended wherein the cell produced by the ten members constitutes a cell that repeats in a uniform pattern of flexible cells, as described in lines 1-2 of Claim 26.

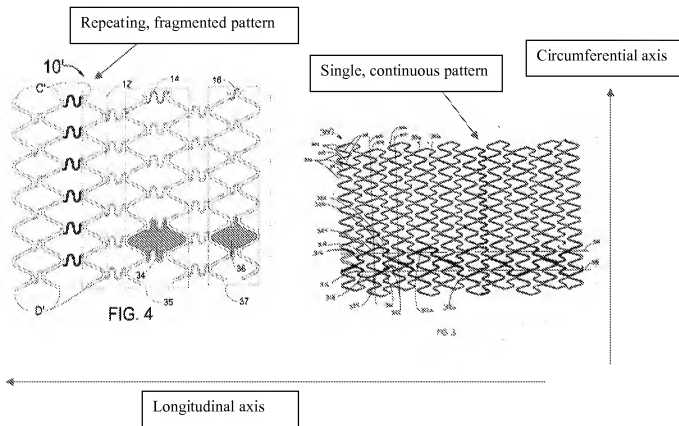
No new matter has been added. No new issues of patentability are raised by the instant amendments. Support for these amendments is found throughout the specification, inter alia on pages 10, 12, and 14-15, as well as Figures 3 and 5.

**Response To Rejection Under 35 U.S.C. §102(e) Based On Fischell**

Claims 1, 6, 11, 42-47 and 49 have been rejected under 35 U.S.C. §102(e) as anticipated by Fischell (6,190,403). Applicants respectfully disagree with this rejection.

Regarding Claims 1, 6, 42-47 and 49, the Examiner has taken the position that the discrete "flexible links" described by Fischell and identified as "A" in Fischell Fig. 4 match the description of a third loop containing section or second circumferential band of a higher frequency formed of "a single, continuous, generally sinusoidal pattern" extending about a circumferential axis, as described in Claims 1 and 6. On this basis,

the Examiner alleges that Fischell Fig. 4 anticipates the instant claims. Applicants respectfully disagree and assert, as presented in the response dated September 28, 2007, that the links illustrated by Fischell Fig. 4 are not formed of a "single, continuous, generally sinusoidal pattern . . . extending in a continuous band of loops around the circumference of the stent," as required by the instant claims. The illustrations below highlight the distinction, with the respective patterns of Fischell Fig. 4 and Fig. 3 of the instant application highlighted in blue.



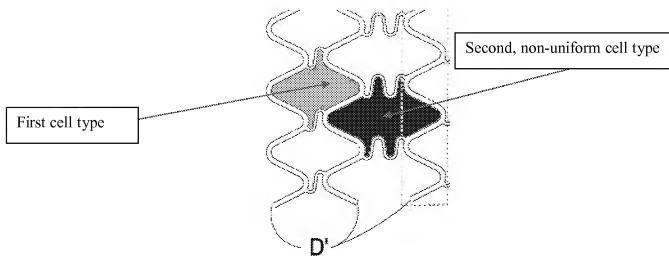
The Examiner states that "element 14 as shown in [Fischell Fig. 4] is clearly qualified for the limitation 'single, continuous, generally sinusoidal pattern' in the claims of the present invention" because Fischell's element 14 is three-dimensional and therefore extends in the circumferential, longitudinal and radial directions. (Office Action at p.5.)

However, the fact that the element 14 in Fischell Fig. 4 can be described as having three dimensions is not sufficient to satisfy the requirement in Claim 1 that the flexible links be formed of a single, continuous pattern “extending in a continuous band of loops around the circumference of the stent.” The Fischell links are not a “single, continuous pattern” and do not form a “continuous band of loops around the circumference of the stent.” As highlighted by the illustration above, the links in Fischell Fig. 4 constitute a fragmented, repeating pattern, wherein each discrete connector extends in the longitudinal direction of the stent as opposed to the single, continuous pattern of the figure of the instant application. Applicants respectfully request reconsideration from the Examiner, particularly on the basis that the links illustrated by Fischell Fig. 4 clearly are not formed of a single, continuous pattern extending in a continuous band of loops around the circumference of the stent.

In addition, Claim 1 describes a third loop containing section of higher frequency that is “also extending in a continuous band of loops around the circumference of the stent,” indicating a comparison with the preceding first and second loop containing sections. Both the first and second loop containing sections are described as “extending in the circumferential direction,” which, as seen in Fig. 3, indicates that the sections extend around the circumference of the stent in a single unbroken pattern. By comparison, Fischell Fig. 4 illustrates links that comprise a plurality of short segments, none of which extend “in a continuous band of loops around the circumference of the stent” in a manner comparable to the first and second loop containing sections of Claim 1.

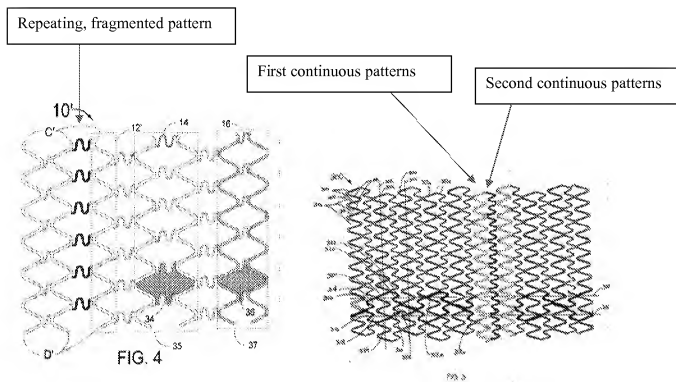
Furthermore, Claim 1 describes a third loop containing section that is “alternately joined to . . . first and second loop containing sections.” Likewise, Claim 6 describes a second circumferential band that is “periodically coupled to . . . first bands.” Where the higher-frequency sections take the form of links that connect only once to each adjacent loop containing section or circumferential band, the terms “alternately” and “periodically” lose all meaning, because each said flexible link is attached to each adjacent band or section only once and not in an alternating or periodic fashion.

Lastly, Claim 1 requires that the first, second and third loop containing sections form “a uniform pattern of flexible cells,” which is not met by Fischell Fig. 4, as highlighted in the illustration below.



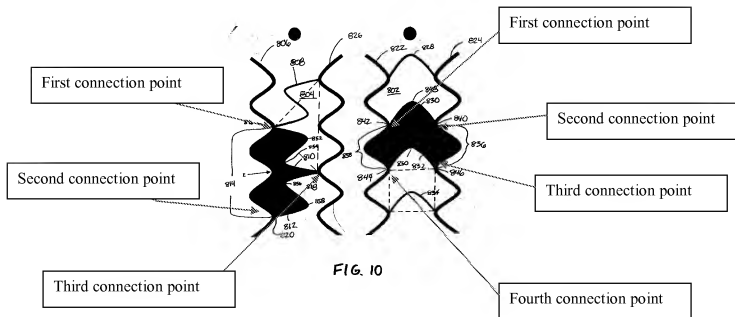
Regarding Claim 11, applicants repeat that Fischell fails to teach flexible links formed of a single, continuous pattern extending around the circumference of the stent. Claim 11 describes a third loop containing section of higher frequency that forms a “second single generally sinusoidal pattern.” The word “second” in that phrase refers back to the first and second loop containing sections, which form the “first continuous

generally sinusoidal pattern.” Hence, the first, second and third loop containing sections resemble one another insofar as they are formed of a continuous pattern as illustrated by Fig. 3. By contrast, the links taught by Fischell Fig. 4 are not so comparable to the first and second loop containing sections because they extend in a different direction and are not continuous around the circumference of the stent. The links of Fischell Fig. 4 (blue) cannot be described as a “second” continuous pattern formed because they do not extend around the circumference of the stent as a single continuous structure.

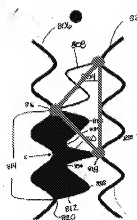


In addition, the Examiner has taken the position that Fischell Fig. 4 shows “triangular” cells formed by first, second and third loop containing sections as recited by Claim 11. Applicants respectfully disagree on the basis that the definition of a “triangular cell” is provided in the Specification at page 17 as “cells . . . of the present invention, which have three points” where the patterns connect. The Specification

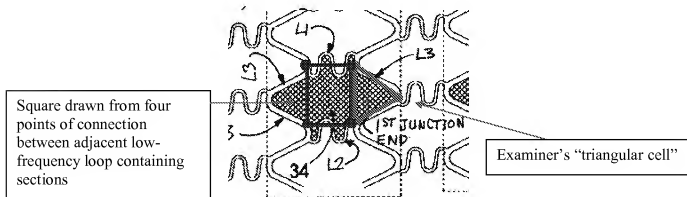
references Fig. 10, provided below, which provides an example of a "triangular cell" (804) compared alongside a "square cell" (802), as defined in the instant application as "cells . . . which have four points" where the patterns connect.



It is insufficient, as presented by the Examiner, that "at least 3rd loop containing sections and first junction end have a triangular configuration," to meet the definition of a triangular cell as provided by the Specification of the instant application. The definition of a triangular cell requires that the cell be formed of a triangle, i.e., wherein within a single cell, there are only three points of connection between adjacent low-frequency loop containing sections. Thus, a triangular shape can be recognized by drawing a line from each point of connection forming the cell, as follows.



The alleged “triangular configuration” suggested by the Examiner between the third loop containing section and the first junction end does not constitute a cell considered by itself, as illustrated below.



The portion of the cell discussed by the Examiner does not describe the entire cell, which has four points of connection between adjacent low-frequency sections. The cell taught by Fischell Fig. 4 therefore forms a “square cell” as defined by the specification of the instant application.

For these reasons, Fischell does not teach or suggest a stent having triangular cells as recited in the instant claims. Reconsideration and withdrawal of the rejections

under 35 U.S.C. §102(e) as to Claims 2, 6, 22, 42-47 and 49 is respectfully requested for the above reasons.

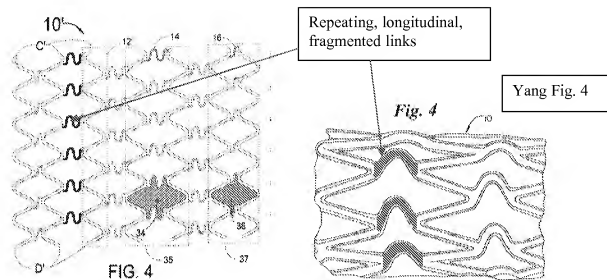
**Response to 35 U.S.C. §103 Rejections Based On Fischell In View Of Yang**

Claims 3, 8 and 28 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Fischell (6,190,403) as applied to claims 1, 6 and 26, and further in view of Yang et al (6,120,847). Applicants respectfully disagree with this rejection.

The Examiner states that Fischell discloses in Fig. 4 substantially all limitations as recited in the claims of the present application, except for drug coating of the stent for local treatment of a blood vessel. The Examiner further states that it is well known in the art to form a drug coating for a stent so that one can provide a local treatment for a blood vessel, as evidenced by Yang. Applicants respectfully disagree.

As discussed above, Fischell fails to describe a stent with a single continuous, generally sinusoidal loop containing section or circumferential band extending in a continuous band of loops around the circumference of the stent. Rather, Fischell describes multiple fragmented links extending longitudinally along the stent. Yang teaches a similar pattern of disconnected flexible links that do not form a single continuous pattern around the circumference of the stent but rather are multiple fragmented links which extend longitudinally, as shown below.





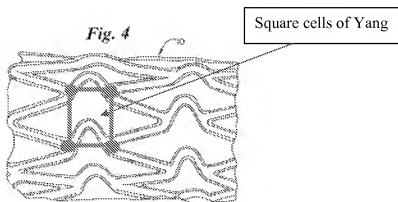
Yang therefore does not remedy this deficiency of Fischell.

Likewise, Yang does not remedy the other deficiencies of Fischell in light of the instant application, as discussed above. First, Claim 1 of the instant application describes a third loop containing section of higher frequency that is “also extending in a continuous band of loops around the circumference of the stent,” indicating a comparison with the preceding first and second loop containing sections. In both Fischell and Yang, the sections connected by the links form a continuous band of loops around the circumference of the stent, in contrast to the connectors of both, which as illustrated above, do not form a continuous band of loops around the circumference of the stent. Hence, the word “also” in Claim 1 of the instant application cannot be applied to either Fischell or Yang and Yang therefore fails to remedy this deficiency of Fischell.

Second, Claim 1 of the instant application describes a third loop containing section that is “alternately joined to . . . first and second loop containing sections.” Likewise, Claim 6 describes a second circumferential band that is “periodically coupled

to . . . first bands." By contrast, the links in both Fischell and Yang as shown above each connect only once to the first and second sections without continuing further to satisfy the recitations in Claim 1 or Claim 6 of the instant application. In view of Fischell Fig. 4 or Yang, the terms "alternately" and "periodically" lose all meaning, because the links taught by either are attached to each respective adjacent band or section only once and not in an alternating or periodic fashion.

Lastly, Fischell does not teach a cell made of triangular cells, as required by Claims 1 and 11. Yang likewise fails to teach or suggest a stent having triangular cells, but rather describes a stent comprised entirely of square cells as shown below.



Yang therefore does not remedy the deficiency of Fischell because it does not describe a stent which has triangular cells, as defined at page 17 of the instant application. In fact, Yang teaches away from the current invention because it describes only square-cell stents (see Yang, Figures 1-4). In contrast, the present invention provides a specific triangular cell stent on which medicine is coated. One skilled in the art would not reach the claimed invention if he combined Fischell and Yang because neither references, alone or in combination, teaches or suggests the claimed stents.

Reconsideration and withdrawal of the rejections under 35 U.S.C. §103(a) as to Claims 3, 8 and 28 is respectfully requested for the above reasons.

**Response to 35 U.S.C. §103 Rejections Based On Berry**

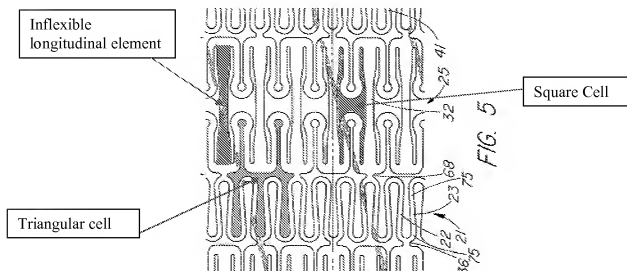
Claim 26 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Berry et al (6,231,598). Applicants respectfully disagree with this rejection.

The Examiner states that Berry Fig. 5 shows a stent having cells with wider members and narrower members, wherein the narrower elements are designed for flexibility and the wider elements are designed for radial strength to support a blood vessel. The Examiner acknowledges that Berry discloses other types of cells, contrary to the recitations of instant Claim 26. However, the Examiner states that the cells allegedly held in common between Berry and the present application are "essential structures," and therefore it would be obvious to one of ordinary skill in the art to construct a stent without these other types of cells which are "not as important" according to the Examiner.

Applicants respectfully disagree with the Examiner's position that Berry discloses substantially all limitations recited in Claim 26 of the present application. Claim 26 recites a stent "consisting essentially of a uniform pattern of flexible cells," wherein "each of the flexible cells" "consists essentially" of ten members that form a uniform pattern of flexible cells. The MPEP defines the phrase "consisting essentially of" as a transitional phrase that "limits the scope of a claim to the specified materials or steps and those that do not materially affect the basic and novel characteristic(s) of the claimed invention." MPEP 2111.03 (internal quotations omitted); see also In re Herz, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976). Thus, the limitation "uniform

pattern of flexible cells" limits the scope of Claim 26 except to those teachings that do not materially affect that basic characteristic of the claimed stents.

By contrast, the cells in a stent as taught by Berry are neither uniform nor uniformly flexible. As illustrated below, the triangular cells of the Berry stent identified by the Examiner are longitudinally adjacent to sections containing an inflexible longitudinal element.



The presence of these inflexible longitudinal elements materially affects the basic characteristic of the stent in that, upon expansion, the inflexible sections of the Berry stent are incapable of flexing in the longitudinal direction. As described in the Berry reference, the inflexible longitudinal elements "maintain the longitudinal orientation [of the stent] during and after expansion of the stent" and thereby play a vital role in the function of the Berry stent. (Berry, 9:25-27) All longitudinal flexibility of the Berry stent is provided by the connections between the adjacent inflexible sections. (See Berry 10:26-31.) Thus, whereas the instant claims recite a uniformly flexible stent, Berry describes an articulated stent formed of inflexible sections interspersed with articulation

points. It is insufficient, as stated by the Examiner, that some of the sections of the Berry stent resemble those of the claimed stent. It is essential to the claimed stents that each cell of the stent combine to form a uniformly flexible stent.

The Berry stent is therefore not "a uniform pattern of flexible cells." Nowhere does Berry suggest that any given cell structure is essential. Rather, the articulated Berry stent teaches away from a uniform pattern of flexible cells. Therefore, Claim 26 is not obvious.

Reconsideration and withdrawal of the rejections under 35 U.S.C. §103(a) as to Claim 26 is respectfully requested for the above reasons.

### **Response to 35 U.S.C. §112 Rejections**

Claims 1, 11 and 49 have been rejected under 35 U.S.C. §112 as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. Applicants respectfully disagree with this rejection.

The Examiner states that the term "the circumferential direction" at line 3 of Claim 1, line 4 of Claim 11 and line 4 of Claim 49 lacks an antecedent basis. However, the absence of an explicit antecedent basis does not mean that the term is necessarily indefinite under 35 U.S.C. §112. The inherent components of recited elements have antecedent basis in the recitation of the components themselves. See MPEP 2173.05(e) ("For example, the limitation 'the outer surface of said sphere' would not require an antecedent recitation that the sphere has an outer surface."); citing Bose Corp. v. JBL, Inc., 274 F.3d 1354, 1359, 61 USPQ2d 1216, 1218-19 (Fed. Cir 2001) (holding that recitation of "an ellipse" provided antecedent basis for "an ellipse having a

major diameter" because "[t]here can be no dispute that mathematically an inherent characteristic of an ellipse is a major diameter").

In the present application, "the circumferential direction" is an inherent component of a stent as recited by the claims. A stent is inherently a tubular structure, upon which a single circumference may be drawn around the curve of the stent. Geometrically, only one circumference may be drawn upon a circle; hence, "the circumferential direction" is necessarily the direction following the circumference of the stent as drawn around the perimeter of the stent at any given point.

Reconsideration and withdrawal of the rejections under 35 U.S.C. §112 as to Claims 1, 11 and 49 is respectfully requested for the above reasons.

### **CONCLUSION**

Based on the foregoing amendments and remarks, applicant respectfully requests reconsideration and withdrawal of the rejections of the pending claims and requests allowance of this application.

**AUTHORIZATION**

The Commissioner is hereby authorized to charge any additional fees which may be required for consideration of this Amendment to Deposit Account No. 50-4387, Order No. 92077.003.

In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. 50-4387, Order No. 92077.003.

Respectfully submitted,  
Cadwalader, Wickersham & Taft LLP

Dated: May 5, 2008

By: /s/ Andrew C. Chien  
Andrew C. Chien  
Registration No. 59,798

Address:  
Cadwalader, Wickersham & Taft LLP  
One World Financial Center  
New York, NY 10281  
(212) 504-6000 Telephone  
(212) 504-6666 Facsimile